Registration Decision RD2014-22

Thyme Oil and Wintergreen Oil

(publié aussi en français)

8 August 2014

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

ISSN: 1925-0932 (print)
1925-0940 (online)

Catalogue number: H113-25/2014-22E (print version)
H113-25/2014-22E-PDF (PDF version)

© Her Majesty the Queen in Right of Canada, represented by the Minister of Health Canada, 2014

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.

Registration Decision for Thyme Oil and Wintergreen Oil

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of TyraTech Thyme Oil Technical, TyraTech Wintergreen Oil Technical, TyraTech Drain Fly Killer and TyraTech TechDust, containing the technical grade active ingredients thyme oil and wintergreen oil. TyraTech Drain Fly Killer kills drain flies (moth flies), fruit flies, phorid flies, house flies, cockroaches, crickets, spiders and springtails on contact. TyraTech TechDust kills ants, bed bugs, cockroaches, crickets, fleas, spiders, silverfish and wasps on contact.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2014-07, *Thyme Oil and Wintergreen Oil*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for thyme oil and wintergreen oil and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2014-07. This decision is consistent with the proposed registration decision stated in PRD2014-07.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2014-07, *Thyme Oil and Wintergreen Oil* that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

---

1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Are Thyme Oil and Wintergreen Oil?

Thyme oil and wintergreen oil are the active ingredients in the end-use products, TyraTech Drain Fly Killer and TyraTech TechDust. Both products are used indoors and outdoors around structures. TyraTech Drain Fly Killer kills drain flies (moth flies), fruit flies, phorid flies, house flies, cockroaches, crickets, spiders and springtails on contact. TyraTech TechDust kills ants, bed bugs, cockroaches, crickets, fleas, spiders, silverfish and wasps on contact.

Health Considerations

Can Approved Uses of Thyme Oil and Wintergreen Oil Affect Human Health?

Thyme oil and wintergreen oil are unlikely to affect human health when used according to label directions.

Exposure to thyme oil and wintergreen oil may occur when applying the end-use products or when people enter a freshly treated site. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

The technical grade active ingredient thyme oil is expected to be of low acute toxicity by the oral, dermal, and inhalation routes; corrosive to eyes and skin, and a skin sensitizer.

The technical grade active ingredient wintergreen oil is expected to be moderately acutely toxic by the oral route, low toxicity by the dermal and inhalation routes, severely irritating to eyes, moderately irritating to skin, and is not a skin sensitizer.

Human exposure from the commercial uses of TyraTech Drain Fly Killer and TyraTech TechDust are not expected to be of concern due to the low toxicity of the end-use products, and the precautionary and hygiene statements present on the end-use product labels that are aimed at mitigating exposure.

Residues in Water and Food

Dietary risks from thyme oil and wintergreen oil on food and water are not of concern.

TyraTech Drain Fly Killer and TyraTech TechDust are not intended for application to food. Also, the end-use product labels instruct not to contaminate food and water with the end-use products; therefore, exposures to thyme oil and wintergreen oil through food from the end-use product uses are anticipated to be negligible.

No risks due to exposure from drinking water are anticipated as thyme oil and wintergreen oil are unlikely to persist in the environment to the extent that it could be consumed in drinking water.

Risks From Handling Thyme Oil and Wintergreen Oil

Risks are not of concern when thyme oil and wintergreen oil are used according to label directions, which include precautionary statements.

TyraTech Drain Fly Killer and TyraTech TechDust are to be applied by commercial applicators for application indoors and outdoors around commercial, institutional, industrial and residential areas.

There is minimal occupational exposure concern from TyraTech Drain Fly Killer, which is a ready-to-use product. Occupational exposure can occur during loading, application, and clean-up activities for TyraTech TechDust. However, risks from exposure are not of concern when workers follow label directions which include exposure mitigation measures, such as personal protective equipment, cautionary, and hygiene statements on the end-use product labels. Moreover, the end-use product labels have mitigative measures to minimize bystander exposure and post-application exposure.

Environmental Considerations

What Happens When Thyme Oil and Wintergreen Oil Are Introduced Into the Environment?

The active ingredients, thyme oil (containing thymol) and wintergreen oil (containing methyl salicylate), are naturally occurring constituents of common plant species, such as thyme (*Thymus vulgaris*) and teaberry (*Gaultheria procumbens*), respectively, but are also present in food and other personal care products. Therefore, it is unlikely that the use of TyraTech Drain Fly Killer and of TyraTech TechDust would increase the concentration of thyme oil and wintergreen oil above background levels. Due to the use pattern of these products, the potential for exposure of non-target terrestrial and aquatic organisms to TyraTech Drain Fly Killer and TyraTech TechDust is expected to be low. Therefore, the risk associated with the use of these products at the accepted application rates and use pattern is expected to be negligible.

Value Considerations

What Is the Value of TyraTech Drain Fly Killer and TyraTech TechDust?

TyraTech Drain Fly Killer and TyraTech TechDust contain thyme oil and wintergreen oil to kill various pests found in and around structures.

TyraTech Drain Fly Killer kills drain flies (moth flies), fruit flies, phorid flies, house flies, cockroaches, crickets, spiders and springtails on contact. TyraTech TechDust kills ants, bed bugs, cockroaches, crickets, fleas, spiders, silverfish and wasps on contact. It is unlikely that pests will develop resistance to thyme oil and wintergreen oil. These products can be used in conjunction with other pest control practices and/or in situations where alternatives to conventional pest control products are desired.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the labels of TyraTech Drain Fly Killer and TyraTech TechDust to address the potential risks identified in this assessment are as follows:

Key Risk-Reduction Measures

Human Health

Workers are required to wear a NIOSH approved respirator for prolonged exposure. However, taking into consideration the inhalation irritation potential of the end-use product, a dust mask to prevent short-term exposure to workers is also required.

Based on the hazard profile of the dust formulation, TyraTech TechDust label requires a personal protective equipment statement: When loading and applying the end-use product, and during cleanup/maintenance activities, workers must wear a long-sleeved shirt and pants, waterproof gloves, goggles, a dust mask, shoes, and socks.

To ensure bystander protection, label statements are required on both the end-use product labels to instruct that the end-use products must not be applied in a way that it will contact workers or other persons, either directly or through drift.

To minimize post-application exposure to children and pets especially in locations, such as hospitals, schools, daycare facilities, multi-family housing, veterinary clinics, and nursing homes, the labels must include the following statement: Do not apply in areas accessible to children and pets.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2014-07, *Thyme Oil and Wintergreen Oil*) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act*.